US-PAT-NO: 4857569

DOCUMENT-IDENTIFIER: US 4857569 A

TITLE: Polymer alloy compositions of rod-like aromatic polyamides and polyurethanes

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Abstract Text - ABTX (1):
A novel thermoplastic composition is prepared by intimately **mixing** a polyurethane component with a selected reinforcing amount of a rod-like aromatic polyamide component. The composition exhibits unexpected tensile and modulus properties.

Brief Summary Text - BSTX (2):
The present invention relates to engineering thermoplastic polymer **blends** having high strength and high modulus and a process for making such **blends**. The **blends** are useful for making high performance fibers, films, sheets, rods, and other articles of manufacture.

Brief Summary Text - BSTX (4):
Attempts have been made to prepare materials with improved properties based on the commercial rod-like polymer poly(p-Phenylene Terephthalamide) (PPTA) with various other polymers. These include: PPTA with nylon 6 and nylon 66 by Takayanagi et al (J. Macro Sci. Phys., B17(2), 519, 1980); PPTA with polyvinyl chloride (PVC) by Takayanagi et al (Report on Progress in Polymer Physics in Japan, 26, 319, 1983); PPTA with acrylonitrile-butadiene-styrene (ABS) resins by Takayanagi et al (J. Applied Polymer Sci., Vol. 29,

257-2559, 1984); and
Japanese Pat. No. 0,034,884 which describes forming a composite material of PPTA with epoxy resins in the presence of lactam and isocyanate compounds. **Blends** containing thermosetting resins cannot be readily melt processed and the nylon-PPTA and PVC-PPTA **blends** show only slightly improved properties.

Brief Summary Text - BSTX (5):
Other materials, such as solvent**-blended** polyurethane with polyethylene terephthalate and/or nylon 6 or nylon 66, as described in U.S. Pat. No. 4,448,936 are useful for making leather-like fabrics and do not exhibit the properties of high performance engineering thermoplastics. Engineering properties, however, can be achieved by physically **blending** nylon and polyurethane with an added amount of chopped glass fibers as described in U.S. Pat. No. 4,141,879.

Brief Summary Text - BSTX (15):
In accordance with the present invention, we have unexpectedly discovered that a high performance thermoplastic composition having a novel combination of properties can be provided by solution**-blending** one or more thermoplastic polyurethane components and a reinforcing amount of one or more rod-like aromatic polyamide components.

Detailed Description Text - DETX (6):
The polyurethanes employed in this invention are thermoplastic rather than thermosetting. They include the three generic classes of poly-ether, poly-caprolactam, and poly-ester polyurethanes, prepared by condensing diisocynate monomers with diols, diamines, and **mixtures** of the two.

Detailed Description Text - DETX (8):
Various thermoplastic polyurethanes are available from K. J. Quinn Co. under the tradename Q-THANE (various grades); B. F. Goodrich under the tradename ESTANE (various grades); Mobay Chemical under the tradename TEXIN (various grades); A. Schulman under the tradename TPP 293-01; Permuthane under the tradenames U23-800, U24-206, U24-303, U24-700, U24670, U25-405; Thermedics under the tradename **TECOFLEX** (various grades), TECFLIX under the tradename (various grades); Dow Chemical under the tradename **PELLETHANE** (various grades); Petrarch under the tradename RIMPLAST; Prolastomer under the tradename PROLASTIC; LNP under the tradename TF, TFL, and TL (various grades); Polymer Compos. under the tradenames PUGL-40, PUKV-20; BASF under the tradename ELASTOLLAN C (various grades); and Wilson-Fiberfil under the tradename URAFIL.

Detailed Description Text - DETX (10):
Suitable solvents for use in forming the compositions of the present invention include dimethylformamide, dimethylacetamide, dimethylsulfoxide, tetramethylurea, hexamethylphosphoramide, N-methylpyrrolidone, N-acetylpyrrolidone, N-diethylacetamide, dimethylacetamide, hexamethylphosphoramide-.gamma.-lactone and the like. **Mixtures** of these solvents, and combinations of these solvents with inorganic salts such as lithium and calcium chloride can also be utilized.

Detailed Description Text - DETX (12):
The compositions of the invention can be formed either by **blending** two individual solutions of the polyurethane and rod-like polyamide components in a common or mutually compatible solvent, or by polymerizing

the polyurethane
components in a solvent which is itself a solution of the rod-like polyamide
component in a suitable solvent.

Detailed Description Text - DETX (21):
Polyurethane (PU) and rod-like polyamide (PA) solutions are **mixed** to yield
polymer **blends** varying in PA concentration from 0-10%. The individual
solutions are prepared as follows:

Detailed Description Text - DETX (22):
A stock solution containing 100 g PU is prepared by dispersing 33.3 g (0.127
moles) of freshly distilled methylene bis-(4-cyclohexyl isocynate) (Hylene W)
and 62.9 g (0.063 moles) of freshly distilled polytetramethylene ether
(Polymeg) in 850 mL of recently distilled 1-methyl-2-pyrrolidinone (NMP) in a
dry, deaerated reaction flask equipped with overhead stirrer and thermometer.
Approximately eight drops of dibutyltin dilaurate catalyst are added and the
mixture is heated to 70.degree. C. with constant stirring. Reaction is
maintained for two hours, after which the **mixture** is allowed to cool. Then a
chain extender is added on to the existing polymer structure by adding through
a drop funnel a solution of 3.8 g (0.063 moles) of ethylene diamine in 50 mL of
NMP. The temperature is raised to 85.degree. C. and the reaction maintained
for three hours. The PU solution is then allowed to cool. The weight of the
total solution is 1015.5 g.

Detailed Description Text - DETX (23):
A stock solution containing 10 g of PA (polyparaphenyleneterephthalamide) is
prepared by first cooling a **mixture** of 250 mL of dry NMP and 500 mL of
hexamethylphosphoramide (HMPA) to 0.degree. C. in a dry,

deaerated reaction flask equipped with an overhead stirrer and a thermometer. To the cooled solution are added 4.5 g (0.042 moles) of freshly sublimed p-phenylenediamine. After dissolution, 8.5 g (0.042 moles) of terephthaloyl chloride are also added. The temperature of the **mixture** is slowly raised to 70.degree. C. and maintained for five hours. To dissolve the precipitated PA, 37 g (5 weight %) of lithium chloride are added. As the **mixture** cools, the PA goes into solution. The weight of the total solution is 1003.6 g.

Detailed Description Text - DETX (24):

A **blend** is prepared containing 2% PA by **mixing** a 101.5 g sample of the PU solution (containing 10.0 g of PU polymer) with a 20.1 g sample of the PA solution (containing 0.2 g of PA polymer). The resulting **blend** is precipitated into deionized water and chopped to small pieces in a Waring **blender**. The solids are extracted overnight with deionized water in a Soxhlet extractor and then dried under vacuum. The sample weighs 9.4 g, which represents a 92.2% yield.

Detailed Description Text - DETX (26):

Following the procedure of Example 1, a **blend** containing 10% PA is prepared by **mixing** 101.5 g of the PU solution (containing 10.0 g of PU) with 100.4 g of the PA solution (containing 1.0 g of PA). The resulting **blend** is precipitated into deionized water and worked up as described above. The yield of the polymer **blend** is 9.7 g or 88.2%.

Detailed Description Text - DETX (28):

Following the procedure of Example 1, a **blend** containing 4% PA is prepared

by **mixing** 254 g of the PU solution (containing 24.0 g of PU) with 100 g of the
PA solution (containing 1.0 g of PA). The resulting **blend** is precipitated into
deionized water and worked up as described above. The yield of the polymer
blend is 25 g or 100%.

Detailed Description Text - DETX (34):
Rather than **blending** appropriate amounts of two ready-made polymer
solutions, another series of **blends** is prepared by synthesizing a polymer in a
solution that is in itself already a polymer solution. This is accomplished by
preparing the PU solution as described in Example 1 and adding to it the
monomers needed for the PA.

Detailed Description Text - DETX (35):
A **blend** containing 2% is prepared by **mixing** 126.9 g of the PU solution
prepared in Example 1 1 (containing 12.5 g of PU) with an additional 120 mL of
dry NMP in a dry, deaerated reaction flask equipped with an overhead stirrer
and a thermometer. The flask is cooled to 0.degree. C. Freshly sublimed
p-phenylenediamine (0.11 g, 0.001 moles) is added to the solution and the
mixture stirred until the diamine is dissolved. The **mixture** is allowed to stir
at room temperature for three hours. The resulting **mixture** is precipitated
into deionized water and worked up as described in Example 1.

Detailed Description Text - DETX (37):
In the manner described in Example 6, a **blend** containing 10% PA is prepared
by reacting 0.28 g (0.0026 moles) of p-phenylenediamine with 0.53 g (0.0026
moles) of terephthaloyl chloride in 63.0 g of the PU solution prepared in

Example 1 (containing 6.2 g of PU). This polymer **blend** is also precipitated into deionized water and treated as in Example 1.

Detailed Description Text - DETX (39):

Block copolymers of PU and PA are prepared. A block copolymer composed of 70 weight % of PU and 30weight % of PA is prepared by first synthesizing a PU prepolymer from freshly distilled 1,4-butanediol and hexamethylene diisocyanate. To a dry, deaerated reaction vessel equipped with overhead stirrer and containing 100 mL of recently distilled and dried NMP are added 2.74 g (0.0304 moles) of 1,4-butanediol and 4.26 g (0.0253 moles) of hexamethylene diisocyanate. A small amount (4 drops) of dibutyltin dilaurate catalyst are also added. The prepolymer is heated for 1.5 hours at 75.degree. C. with constant stirring. Then 1.36 g (0.0126 moles) of freshly sublimed p-phenylenediamine and 3.59 g (0.0177 moles) of freshly sublimed terephthaloyl chloride are added to the flask and the **mixture** is allowed to come to room temperature while stirring for one hour. The block copolymer is precipitated into methanol, extracted with methanol in a Soxhlet extractor overnight, and dried under vacuum.

Detailed Description Text - DETX (43):

Rather than precipitating it into water, 100 g of the polymer **blend** solution prepared in Example 1 (containing 2% PA) is processed into a film by pouring the **blend** solution into a casting ring and evaporating the solvent under vacuum at 60.degree. C. The resulting film is tough and flexible.

Detailed Description Text - DETX (45):

Another process is to extrude 100 g of the polymer **blend** solution from

Example 1 through a single-hole spinnerette into a quenching bath of deionized water at room temperature to form composite fibers. The resulting fiber is wound onto a roll, which remains immersed in water overnight. It is then dried under vacuum.

Detailed Description Text - DETX (47):

The polymer **blend** prepared in Example 1 is also melt-extruded into a fiber by placing 10 g of the solid material in the barrel of a capillary viscometer and heating it to 120.degree. C. The **blend** is extruded through a 0.05 cm orifice under a force of approximately 100 psi to yield a tough but flexible fiber. A series of mechanical tests are performed following the general procedures of ASTM D638. Tensile strength, elongation at break, and modulus measurements are performed with an Instron load frame and a 50-pound load cell. Melt viscosities are measured with a Theometrics Mechanical Spectrometer. Results showing synergistic interaction in properties for samples of the preferred compositions are summarized in FIGS. 1 to 4.

Detailed Description Text - DETX (48):

The prepolymer is heated for 1.5 hours at 75.degree. C. with constant stirring. Then 1.36 g (0.0126 moles) of freshly sublimed p-phenylenediamine and 3.59 g (0.0177 moles) of freshly sublimed terephthaloyl chloride are added to the flask and the **mixture** is allowed to come to room temperature while stirring for one hour. The block copolymer is precipitated into methanol, extracted with methanol in a Soxhlet extractor overnight, and dried under vacuum.

Detailed Description Text - DETX (52):

Rather than precipitating it into water, 100 g of the polymer **blend** solution prepared in Example 1 (containing 2% PA) is processed into a film by pouring the **blend** solution into a casting ring and evaporating the solvent under vacuum at 60.degree. C. The resulting film is tough and flexible.

Detailed Description Text - DETX (54):
Another process is to extrude 100 g of the polymer **blend** solution from Example 1 through a single-hole spinnerette into a quenching bath of deionized water at room temperature to form a composite fiber. The resulting fiber is wound onto a roll, which remains immersed in water overnight. It is then dried under vacuum.

Detailed Description Text - DETX (56):
The polymer **blend** prepared in Example 1 is also melt-extruded into a fiber by placing 10 g of the solid material in the barrel of a Tinnius-Olsen capillary viscometer and heating it to 120.degree. C. The **blend** is extruded under a force of approximately 100 psi to yield a tough but flexible fiber. A series of mechanical tests is performed. Tensile strength, elongation at break, and modulus measurements are performed with an Instron load frame and a 50-pound load cell. Melt viscosities are measured with a Rheometrics Mechanical Spectrometer.

Detailed Description Text - DETX (58):
84 weight percent of a commercial grade polyurethane, selected from the above list of thermoplastic polyurethanes, is dissolved in a suitable amount of solvent to form a urethane-solvent **mixture**. 4 weight percent of a polyamide, selected from the above list of commercially available rod-like aromatic

polyamides, is then added to the urethane-solvent **mixture**
to form a polymer
blend. The resulting solvent free **blend** is found to have a
modulus about 500%
greater than the modulus of the thermoplastic polyurethane
component of the
blend.

Claims Text - CLTX (1):
1. A novel engineering thermoplastic composition
comprising a homogeneous
polymer **blend** of at least two components:

Claims Text - CLTX (3):
(b) a reinforcing amount of one or more of a rod-like
aromatic polyamide;
said polymer **blend** having an initial modulus of at least
10.sup.3 psi, a
tensile strength of at least 400 psi, and a melt viscosity
at 120.degree. C.
of at least 5.times.10.sup.6 poise.

Claims Text - CLTX (9):
3. A composition of claim 1, wherein said thermoplastic
polyurethane
component of said **blend** is about 85%-99% and said rod-like
aromatic polyamide
component of said **blend** is about 1%-15%.

Claims Text - CLTX (10):
4. A composition of claim 1, wherein said thermoplastic
polyurethane
component of said **blend** is about 90%-98% and said rod-like
aromatic polyamide
component of said **blend** is about 2%-10%.

Claims Text - CLTX (11):
5. A composition of claim 2, wherein said thermoplastic
polyurethane
component of said **blend** is about 85%-99% and said rod-like
aromatic polyamide
component of said **blend** is about 1%-15%.

Claims Text - CLTX (12):
6. A composition of claim 2, wherein said thermoplastic polyurethane component of said **blend** is about 90%-98% and said rod-like aromatic polyamide component of said **blend** is about 2%-10%.

Claims Text - CLTX (14):
8. A composition of claim 1, 2, 3, or 4 wherein said composition is characterized as having a tensile strength of at least 200% greater than the tensile strength of the polyurethane component of the **blend**.

Claims Text - CLTX (15):
9. A composition of claim 1, 2, 3, or 4 wherein said composition is characterized as having a modulus of at least 150% greater than the modulus of the polyurethane component of the **blend**.

Claims Text - CLTX (16):
10. A composition of claims 1, 2, 3, 4, 5, or 6, wherein said composition is formed from a solution of said thermoplastic polyurethane and a solution of said rod-like aromatic polyamide, said solution of said thermoplastic polyurethane being formed by admixing said thermoplastic polyurethane in one or more of a thermoplastic polyurethane compatible solvent, said solution of said rod-like aromatic polyamide being formed by admixing said rod-like aromatic polyamide with one or more of a rod-like aromatic polyamide compatible solvent, said thermoplastic polyurethane compatible solvent or said rod-like aromatic polyamide compatible solvent comprising one or a **mixture** of two or more solvents selected from the following:

Claims Text - CLTX (25):
(i) hexamethylphosphoramide-.gamma.-lactone, or one or a **mixture** of one or
more of

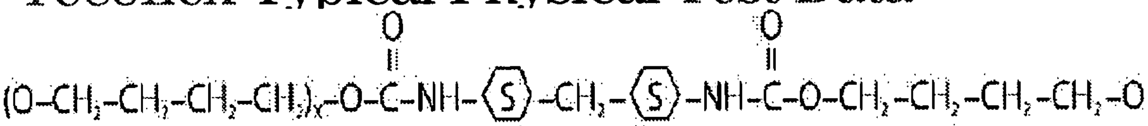
Other Reference Publication - OREF (6):
Flory, "Statistical Thermodynamics of **Mixtures** of
Rod-Like Particles . . .
", Stanford University (06/08/78).

Other Reference Publication - OREF (8):
Krause, "Tables of Polymers That May Be Compatible At
Room Tem.", Polymer
Blends, vol. I (1978).

Other Reference Publication - OREF (9):
Utracki, "Economics of Polymer **Blends**", Polymer Eng. and
Sci., vol. 22, No.
17 (12/82).

Other Reference Publication - OREF (10):
Kamal et al., "Some Solid-State Properties of **Blends** of
Polyethylene
Terephthalate and Polyamide-6,6", Polymer Engineering and
Science, vol. 22, No.
17 (1982).

Tecoflex Typical Physical Test Data



CLEAR GRADES

	ASTM Test	EG-80A	EG-85A	EG-93A	EG-100A	EG-60D	EG-65D	EG-68D	EG-72D
Durometer (Shore Hardness)	D2240	72A	77A	87A	94A	51D	60D	63D	67D
Specific Gravity	D792	1.04	1.05	1.08	1.09	1.09	1.10	1.10	1.11
Flexural Modulus (psi)	D790	1,000	2,300	3,200	10,000	13,000	37,000	46,000	92,000
Ultimate Tensile (psi)	D412	5,800	6,200	7,700	8,200	8,300	8,300	8,300	8,100
Ultimate Elongation (%)	D412	660	550	390	370	360	360	350	310
Tensile (psi)	D412								
at 100% Elongation		300	600	1,000	1,600	1,800	2,200	2,600	3,400
at 200% Elongation		500	900	1,900	3,000	2,900	3,000	3,700	4,800
at 300% Elongation		800	1,400	4,300	5,600	5,600	6,000	6,300	7,100
Melt Index (gm/10 min at 2160 gm load)	D1238	3.5 (175°C)	4.0 (165°C)	5.3 (170°C)	4.8 (175°C)	3.4 (175°C)	3.8 (175°C)	3.5 (175°C)	4.0 (175°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006

RADIOPAQUE GRADES (20% loading of barium sulfate)

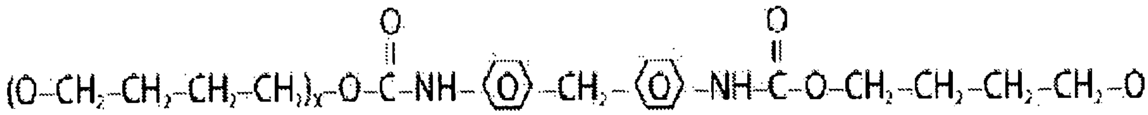
	ASTM Test	EG-80A-B20	EG-85A-B20	EG-93A-B20	EG-100A-B20	EG-60D-B20	EG-65D-B20	EG-68D-B20	EG-72D-B20
Durometer (Shore Hardness)	D2240	73A	83A	90A	93A	55D	63D	73D	75D
Specific Gravity	D792	1.24	1.25	1.27	1.29	1.32	1.32	1.30	1.31
Flexural Modulus (psi)	D790	1,200	2,700	5,000	17,000	27,000	82,000	76,600	125,000
Ultimate Tensile (psi)	D412	5,100	5,600	6,900	7,100	7,500	7,000	7,000	6,500
Ultimate Elongation (%)	D412	710	630	440	370	370	320	340	270
Tensile (psi)	D412								
at 100% Elongation		400	700	1,000	1,700	2,000	2,900	2,700	3,600
at 200% Elongation		600	1,100	1,800	2,600	3,100	3,600	3,500	4,200
at 300% Elongation		900	1,600	3,100	4,900	5,600	6,000	5,600	NA
Melt Index (gm/10 min at 2160 gm load)	D1238	4.4 (165°C)	5.4 (175°C)	8.0 (170°C)	4.8 (175°C)	3.4 (175°C)	3.8 (175°C)	3.5 (175°C)	5.5 (170°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006

NOTE: This test data represents the most recent additions and updates to the Tecoflex family of aliphatic polyether-based polyurethane and should be referenced accordingly. These test results are based on small samples of Tecoflex polyurethane and do not necessarily represent average results from larger test samples. This information should not be used for establishing engineering or manufacturing guidelines.

RADIOPAQUE GRADES (40% loading of barium sulfate)

	ASTM Test	EG-80A-B40	EG-85A-B40	EG-93A-B40	EG-100A-B40	EG-60D-B40	EG-65D-B40	EG-72D-B40
Durometer (Shore Hardness)	D2240	78A	86A	95A	98A	65D	78D	82D
Specific Gravity	D792	1.48	1.50	1.52	1.53	1.53	1.54	1.55
Flexural Modulus (psi)	D790	1,500	3,700	4,700	14,000	27,000	97,000	179,000
Ultimate Tensile (psi)	D412	4,700	4,900	6,500	6,600	6,800	6,200	5,700
Ultimate Elongation (%)	D412	660	590	430	390	370	330	190
Tensile (psi)	D412							
at 100% Elongation		500	900	1,400	2,100	2,200	3,000	4,300
at 200% Elongation		900	1,400	2,000	2,700	2,900	3,500	NA
at 300% Elongation		1,200	1,800	3,100	4,300	4,700	5,300	NA
Melt Index (gm/10 min at 2160 gm load)	D1238	7.2 (170°C)	5.0 (170°C)	4.8 (170°C)	4.0 (170°C)	3.0 (175°C)	3.4 (175°C)	3.5 (175°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.008	.004-.008	.004-.006

Tecothane Typical Physical Test Data



CLEAR GRADES

	ASTM Test	TT-1074A	TT-1085A	TT-1095A	TT-1055D	TT-1065D	TT-1069D	TT-1072D	TT-1075D-M
Durometer (Shore Hardness)	D2240	75A	85A	94A	54D	64D	69D	74D	75D
Specific Gravity	D792	1.10	1.12	1.15	1.16	1.18	1.18	1.18	1.19
Flexural Modulus (psi)	D790	1,300	3,000	8,000	18,000	26,000	44,000	73,000	180,000
Ultimate Tensile (psi)	D412	6,000	7,000	9,000	9,600	10,000	8,800	9,000	8,300
Ultimate Elongation (%)	D412	550	450	400	350	300	310	275	150
Tensile (psi)	D412								
at 100% Elongation		500	800	1,300	2,500	2,800	3,200	3,700	3,600
at 200% Elongation		700	1,000	2,100	3,800	4,600	4,200	3,900	NA
at 300% Elongation		1,100	1,600	4,300	6,500	7,800	NA	NA	NA
Melt Index (gm/10 min at 2160 gm load)	D1238	3.5 (205°C)	4.0 (205°C)	3.8 (210°C)	4.0 (210°C)	2.0 (210°C)	3.0 (210°C)	2.0 (210°C)	5.0 (210°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006	.004-.006

RADIOPAQUE GRADES (20% loading of barium sulfate)

	ASTM Test	TT-2074A-B20	TT-2085A-B20	TT-2095A-B20	TT-2055D-B20	TT-2065D-B20	TT-2069D-B20	TT-2072D-B20	TT-2075D-B20
Durometer (Shore Hardness)	D2240	77A	87A	97A	55D	67D	70D	75D	77D
Specific Gravity	D792	1.30	1.32	1.35	1.36	1.38	1.38	1.38	1.40
Flexural Modulus (psi)	D790	1,800	3,500	8,500	19,000	31,000	50,000	80,000	190,000
Ultimate Tensile (psi)	D412	5,200	6,600	8,200	8,600	8,700	7,500	7,900	7,600
Ultimate Elongation (%)	D412	650	600	450	360	300	320	270	200
Tensile (psi)	D412								
at 100% Elongation		500	700	1,600	2,500	3,100	3,500	3,800	3,600
at 200% Elongation		700	1,000	2,000	3,600	4,500	4,000	4,600	NA
at 300% Elongation		1,000	1,500	3,500	6,000	7,500	6,500	NA	NA
Melt Index (gm/10 min at 2160 gm load)	D1238	8.0 (195°C)	5.5 (195°C)	7.0 (205°C)	4.5 (210°C)	4.7 (210°C)	9.0 (210°C)	5.0 (210°C)	7.5 (210°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.004-.008	.004-.008	.004-.008	.004-.006	.004-.006

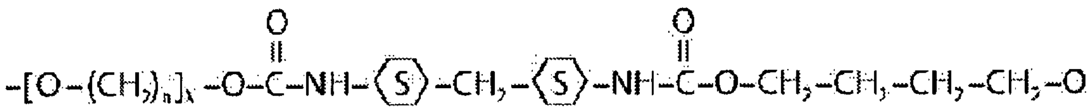
NOTE: TT-1069, TT-1072, TT-2069D-B20 and TT-2072D-B20 are excellent candidates for over-the-needle applications.

These test results are based on small samples of Tecothane polyurethane and do not necessarily represent average results from larger test samples. This information should not be used for establishing engineering or manufacturing guidelines.

RADIOPAQUE GRADES (40% loading of barium sulfate)

	ASTM Test	TT-2074A-B40	TT-2085A-B40	TT-2095A-B40	TT-2055D-B40	TT-2065D-B40	TT-2075D-B40
Durometer (Shore Hardness)	D2240	83A	88A	97A	64D	75D	84D
Specific Gravity	D792	1.57	1.58	1.59	1.62	1.64	1.65
Flexural Modulus (psi)	D790	2,800	3,800	12,000	24,000	58,000	421,000
Ultimate Tensile (psi)	D412	3,600	4,200	6,700	6,800	6,900	7,100
Ultimate Elongation (%)	D412	700	540	470	380	330	25
Tensile (psi)	D412						
at 100% Elongation		600	1,000	1,700	2,700	3,100	NA
at 200% Elongation		800	1,100	2,100	3,300	3,800	NA
at 300% Elongation		1,000	1,700	3,500	5,000	6,000	NA
Melt Index (gm/10 min at 2160 gm load)	D1238	8.2 (195°C)	9.8 (195°C)	4.2 (195°C)	3.7 (195°C)	7.7 (200°C)	7.5 (200°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.004-.008	.004-.008	.004-.006

Tecophilic Typical Physical Test Data



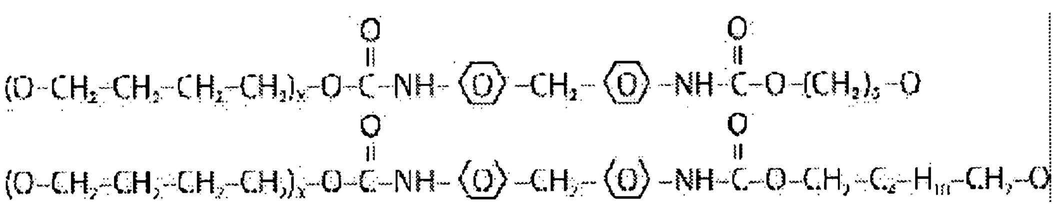
n=2 for PEG or 4 for PTMEG

	ASTM Test	HP-60D-20	HP-60D-35	HP-60D-60	HP-93A-100
Durometer (Shore Hardness)	D2240	43D	42D	41D	83A
Specific Gravity	D792	1.12	1.12	1.15	1.13
Flexural Modulus (psi)	D790	4300	4000	4000	2900
Ultimate Tensile (psi)	D412				
Dry		8900	7800	8300	2200
Wet		5100	4900	3100	1400
Ultimate Elongation (%)	D412				
Dry		430	450	500	1040
Wet		390	390	300	620

The values reported above are based on a small sample base and should be used as approximations only.

Note: Although no physical test data is currently available for Tecogel, this hydrogel can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of the dry resin.

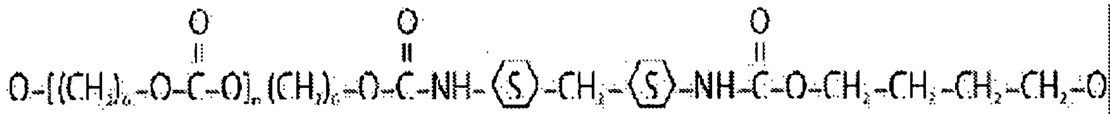
Tecoplast Typical Physical Test Data



	ASTM Test	Series TP-470 Clear Resins	Series OP-770 Opaque Resins
Durometer (Shore Hardness)	D2240	82D	82D
Specific Gravity	D792	1.18	1.19
Flexural Modulus (psi)	D790	300,000	250,000
Ultimate Tensile (psi)	D638	10,000	9,000
Ultimate Elongation (%)	D638	50%	50%
Drop Weight Impact	D3029 (G)		
Unannealed		30 in-lb	40 in-lb
Annealed*		>40 in-lb	>40 in-lb
Heat Deflection	D648		
264 psi, unannealed		150°F (65°C)	140°F (61°C)
264 psi, annealed*		165°F (75°C)	150°F (65°C)
Mold Shrinkage (in/in)	D955	.0014	.0014

*Samples were annealed for 4 hours at 150°F (65°C)
The properties reported above are based on a small sample base and should be used as approximations only.

Carbothane Typical Physical Test Data



CLEAR GRADES

	ASTM Test	PC-3575A	PC-3585A	PC-3595A	PC-3555D	PC-3572D
Durometer (Shore Hardness)	D2240	73A	84A	95A	60D	71D
Specific Gravity	D792	1.15	1.15	1.15	1.15	1.15
Flexural Modulus (psi)	D790	620	1,500	4,500	24,000	92,000
Ultimate Tensile (psi)	D412	5,300	6,000	7,100	7,300	8,500
Ultimate Elongation (%)	D412	470	410	380	370	360
Tensile (psi)	D412					
at 100% Elongation		300	600	1,000	1,500	3,300
at 200% Elongation		500	900	1,900	2,300	4,100
at 300% Elongation		900	2,200	4,400	4,700	6,900
Melt Index (gm/10 min at 2160 gm load)	D1230	5.0 (210°C)	3.0 (205°C)	3.9 (210°C)	3.3 (210°C)	4.8 (210°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.006

RADIOPAQUE GRADES (20% loading of barium sulfate)

	ASTM Test	PC-3575A-B20	PC-3585A-B20	PC-3595A-B20	PC-3555D-B20	PC-3572D-B20
Durometer (Shore Hardness)	D2240	73A	89A	96A	60D	75D
Specific Gravity	D792	1.35	1.35	1.35	1.35	1.35
Flexural Modulus (psi)	D790	860	1,700	8,600	25,000	141,000
Ultimate Tensile (psi)	D412	6,000	6,000	8,100	8,000	7,800
Ultimate Elongation (psi)	D412	530	480	410	400	310
Tensile (psi)	D412					
at 100% Elongation		400	700	1,000	1,700	3,500
at 200% Elongation		700	1,100	1,700	2,700	4,400
at 300% Elongation		1,200	2,000	3,400	4,900	6,800
Melt Index (gm/10 min at 2160 gm load)	D1238	7.0 (210°C)	6.9 (190°C)	4.8 (205°C)	3.2 (210°C)	2.0 (210°C)
Mold Shrinkage (in/in)	D955	.008-.012	.008-.012	.006-.010	.006-.010	.004-.006

These test results are based on small samples of Carbothane polyurethane and do not necessarily represent average results from larger test samples. This information should NOT be used for establishing engineering or manufacturing guidelines.

Solution Grade Polymers

Although all Thermedics Polymer Products' polymers can be dissolved in certain solvents, certain grades have been developed specifically for use in solution casting or for coating of medical products. The solution grades differ from the extrusion grades in that they contain no melt processing lubricants.

Tecoflex solution grade polyurethanes are available in four hardnesses; Tecophilic has three solution grade products.

SOLUTION PROCESSIBLE GRADES

Tecoflex	**Tecophilic**
SG-80A	SP-80A-150
SG-85A	SP-93A-100
SG-93A	SP-60D-60
SG-60D	

*Note last two or three characters of the Tecophilic Product represent the approximate equilibrium water content.

Solution processing guidelines can be found in **Thermedics Polymer Products' Processing Information Booklet**

Tec flex® Aliphatic Polyurethane

Effect of Co60 Sterlization on Long-Term Stability

Procedure:

Tecoflex extruded tapes were sterilized with single (2.5 megarads and double 5 megarad total) doses of Gamma radiation. The retention of physical properties of these tapes has been recorded at 3 intervals over a 15-month period (see chart). Testing was done in compliance with ASTM D-638-72 for tensile and elongation properties of plastics.

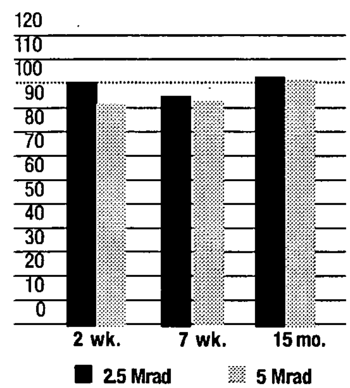
Results:

As the graphs indicate, even after 5 megarads exposure and 15 months post irradiation, the Tecoflex family of aliphatic polyurethanes continues to retain its outstanding physical properties.

Tensile Strength Change after Co60 Exposure

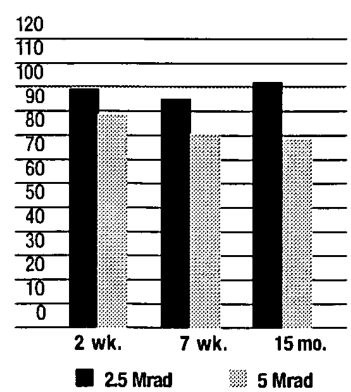
EG80A

Co^{60} Exposure	2 Weeks	7 weeks	15 Months
2.5 Mrad	-2%	-7%	0%
5 Mrad	-11%	-8%	-1%



EG60D

Co^{60} Exposure	2 Weeks	7 Weeks	15 Months
2.5 Mrad	-3%	-8%	-2%
5 Mrad	-15%	-21%	-25%



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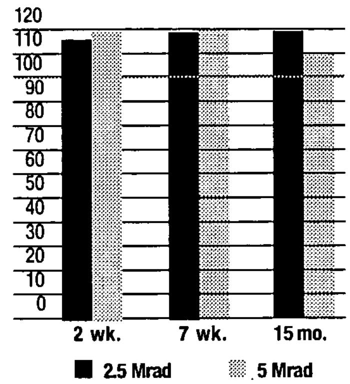
Elongation Change after Co^{60} Exposure

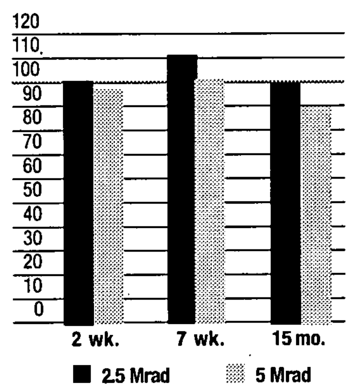
EG60D

Co^{60} Exposure	2 Weeks	7 Weeks	15 Months
2.5 Mrad	+12%	+16%	+7%
5 Mrad	+16%	+17%	+14%

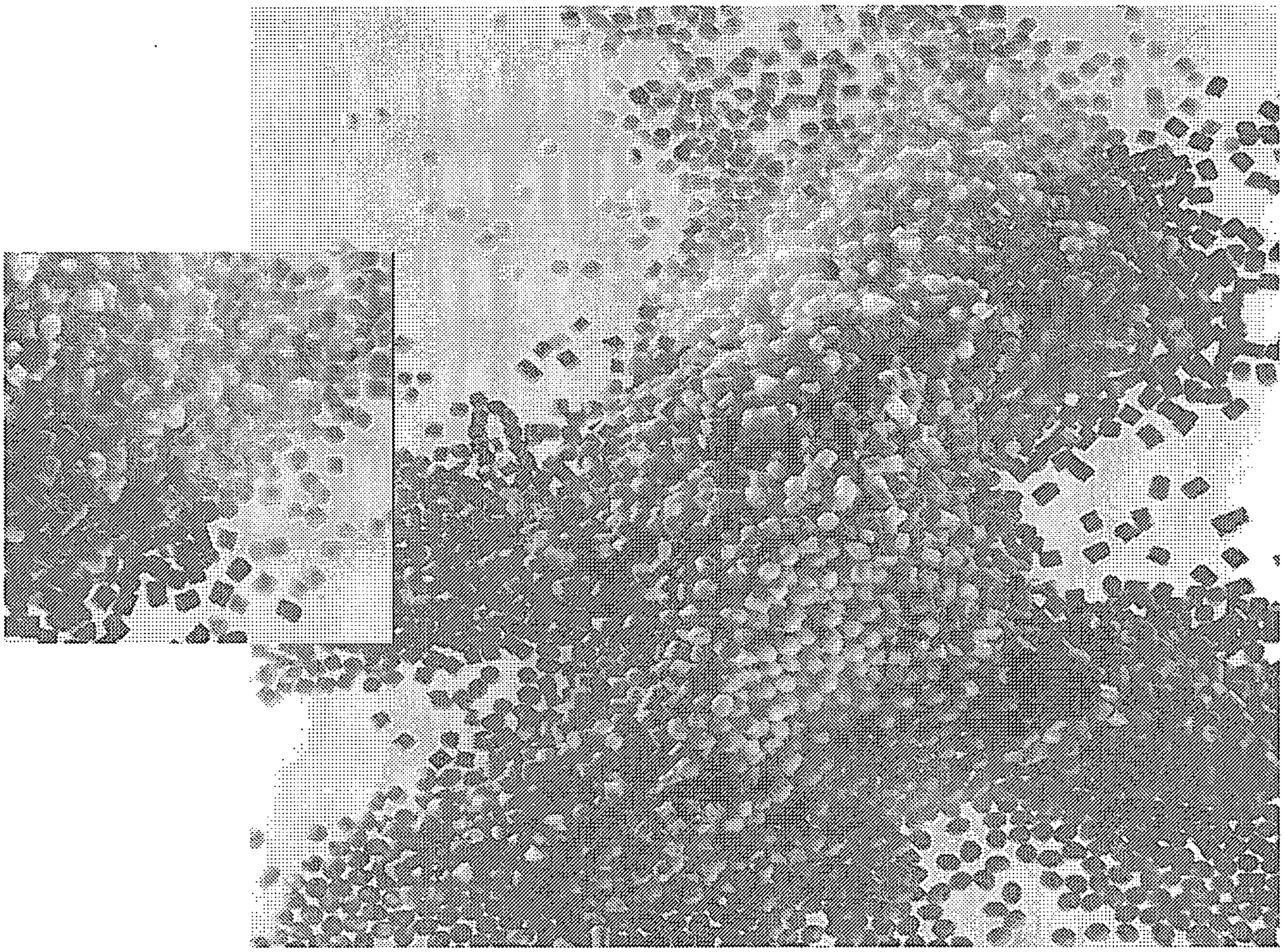


EG60D

Co^{60} Exposure	2 Weeks	7 Weeks	15 Months
2.5 Mrad	-3%	+13%	0%
5 Mrad	-5%	+5%	-10%



Technical Information



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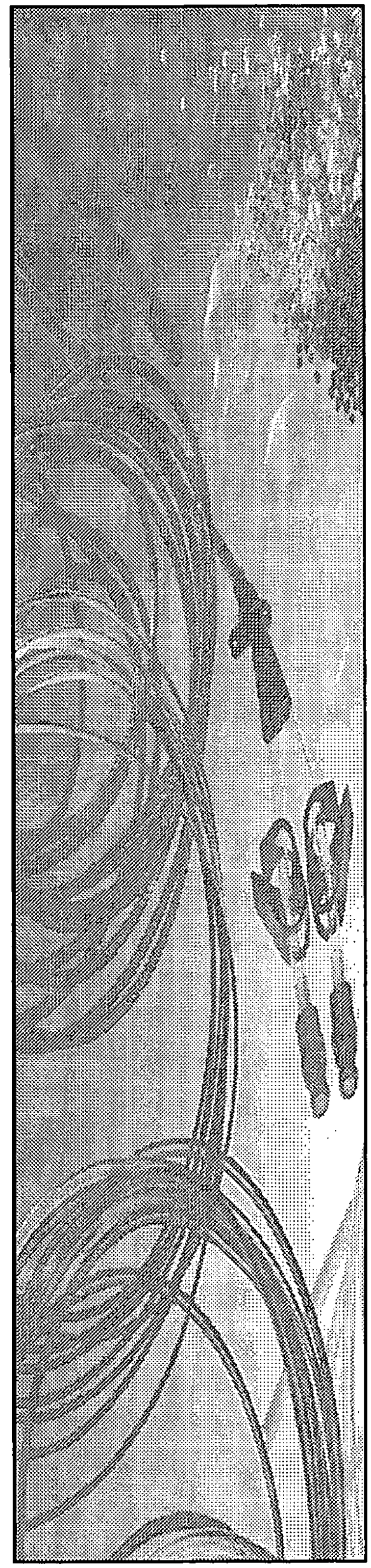
10/2003

The Versatility of Polyurethane



The proper selection of a material in the development of a medical device is critical for the device engineer and the design team involved. Thermedics Polymer Products offers that team a family of thermoplastic polyurethanes that have been specially formulated and manufactured for medical applications.

Thermedics Polymer Products' polyurethanes are available in a wide range of durometers, from 72 Shore A to 84 Shore D, making them useful for a large variety of medical devices and components. Thermedics Polymer Products' polyurethanes (TPU's) exhibit excellent abrasion resistance and flexural endurance as compared to other polymers of similar durometers.

The ease of processing and high strength of polyurethanes makes them the material of choice for soft elastomer applications. Silicone, for example, another common polymer used in low durometer applications, is difficult to extrude and does not bond easily to other components made of non-silicone materials. Because of the much greater strength of polyurethanes as compared to silicone, the walls of polyurethane tubing can be made much thinner, allowing for either a smaller overall diameter or a larger inside diameter for increased flow — both great benefits for indwelling device applications.

Polyurethanes eliminate the problems associated with other materials used in mid-durometer applications such as PVC, where the dangers of leachable plasticizers become a concern. TPU's also retain their elastomeric characteristics even at low temperatures where PVC becomes brittle.

Thermedics Polymer Products' urethanes compare favorably to harder grade polymers like the fluorinated hydrocarbons. Fluorocarbons are very difficult to bond to other materials and have poor kink resistance. Again, the bondability, strength and processability of our polyurethanes make them a better choice for harder durometer applications.

Most of Thermedics Polymer Products' polyurethanes can be loaded with radiopaque materials for detection on X-ray or fluoroscope and colored for product identification. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixture and superior smoothness of the final polymer. All additives to our polyurethanes are thoroughly screened and carefully tested for chemical stability, biocompatibility and performance in our products before use as a radiopaque or coloring agent.

The many requirements necessary for safe, practical use of an elastomer in medical devices quickly narrows the field of suitable materials. Thermedics Polymer Products' polyurethanes pass the tests of biocompatibility, processability and chemical stability for medical device use. Wide durometer range and smooth radiopaque surfaces enhance Thermedics Polymer Products' standing as the optimal supplier of polyurethane materials for medical device components.

Thermedics' polymers are being used in numerous medical devices from pacemakers, various access devices, PEG tubes and balloons.

The TPU Product Family

Each of our families of resins has unique characteristics that must be considered when selecting a material for your application. The following summaries will guide you in the selection of the proper material for your specific needs.

Tecoflex®

A family of aliphatic, polyether-based TPU's available over a wide range of durometers, colors, and radiopacifiers. These resins are easy to process and do not yellow upon aging. Solution grade versions are candidates to replace latex. Caution must be observed in evaluating these resins, especially the low durometer grades, in long-term implant applications because of the potential for stress cracking.

Tecothane®

A family of aromatic, polyether-based TPU's available over a wide range of durometers, colors, and radiopacifiers. One can expect Tecothane resins to exhibit improved solvent resistance and biostability when compared with Tecoflex resins of equal durometers. As with any aromatic polyurethane, Tecothane resins tend to yellow upon aging or when subjected to radiation sterilization.

Carbothane®

A family of aliphatic, polycarbonate-based TPU's available over a wide range of durometers, colors, and radiopacifiers. This type of TPU has been reported to exhibit excellent oxidative stability, a property which may equate to excellent long-term biostability. This family, like Tecoflex, is easy to process and does not yellow upon aging.

Tecophilic®

A family of aliphatic, polyether-based TPU's which have been specially formulated to absorb equilibrium water contents of up to 150% of the weight of dry resin. Extrusion grade formulations are designed to provide maximum physical properties of thermoformed tubing or other components. Solution grade formulations are designed to provide greater solubility in organic solvents to prepare lacquers for coating applications. **Tecogel,** a new member to the Tecophilic family, is a hydrogel that can be formulated to absorb equilibrium water contents between 500% and 2000% of the weight of dry resin. The materials were designed as a coating cast from an ethanol/water solvent system. Other solvent systems such as THF/water and DMAC can be used. Tecogel is melt processible using modified injection molding and extrusion methods.

Tecoplast®

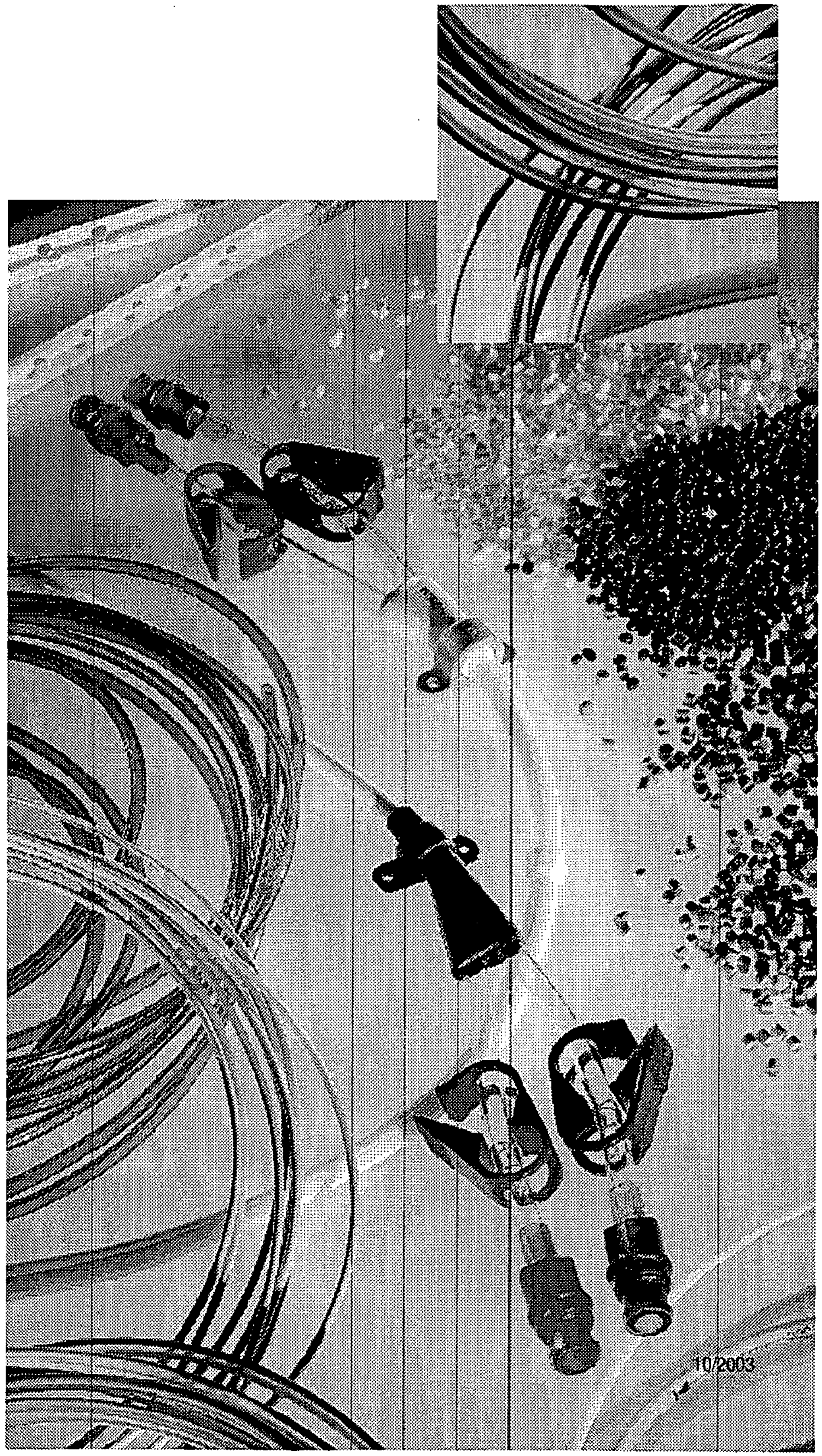
A family of aromatic, polyether-based TPU's formulated to produce rugged injection molded components exhibiting high durometers and heat deflection temperatures. Tecoplast is intended for use as hubs and fittings manufactured as individual components or insert molded onto tubing. Available as clear as well as transparent and opaque colors.

Summary of Differences

Property	Tecothane	Tecoflex	Carbothane	Tecophilic
Yellowing	Significant Concern especially for aesthetic appearance of clear components.	Minor concern	Minor concern	Minor concern
Solvent resistance	Excellent	Low durometers may exhibit considerable swelling and tackiness upon prolonged exposure to polar organic solvents	Similar to Tecoflex	Similar to Tecoflex
Softening at body temperature	Yes	Yes, to an even greater degree	Yes	Yes
Formation of MDA (Methylene Dianiline)	Possible if resin or product is improperly processed	Not possible	Not possible	Not possible
Melt processing Temperatures	High temperatures 195° to 230° C 380° to 450° F	Lower temperatures 155° to 190° C 310° to 375° F	High temperatures 185° to 215° C 365° to 420° F	Lower temperatures 155° to 190° C 310° to 375° F

Committed to

providing medical grade thermoplastic polyurethane resins.



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Thermedics Polymer Products

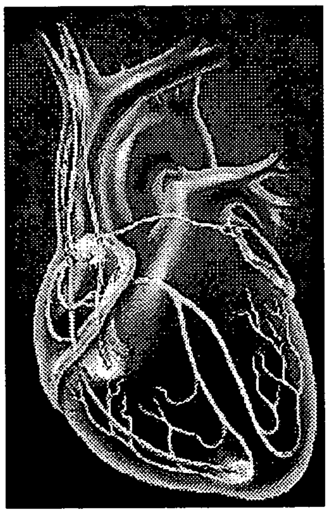
Beginning with the commercial introduction of Tecoflex in 1983, Thermedics Polymer Products has continued to supply the medical device industry with an outstanding array of thermoplastic polyurethanes (TPU's). Each of our family of products — Tecoflex, Tecothane, Carbothane, Tecoplast and Tecophilic has been specifically formulated to have good biocompatibility, flexural endurance, high strength and processing versatility over a wide range of applications. Thermedics Polymer Products' families of TPU's are now being used in many medical devices with new applications continually being found by device manufacturers who encounter demanding tissue or blood contact situations.

Meeting the Challenge

Body tissue and blood present difficult environments for elastomeric components of indwelling medical devices. Such components must be able to withstand extended exposure to hostile aqueous environments at body temperature and the corrosive biochemical composition of blood and body fluids that can degrade many materials. At the same time, the device must cause as few complications to the patient as possible. Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an indwelling medical device. Furthermore, the elastomeric component must be strong and easy to manufacture into small, precise shapes and sizes specified by device designers. For example, it is important to keep catheters as small as possible when they are entering the circulatory system — a common application for cardiovascular diagnostic and clinical devices.

Resins with biocompatibility and biostability are critical components in medical device manufacturing. Thermedics Polymer Products offers a wide variety of thermoplastic polyurethanes that are designated as medical grade biomaterials having passed either USP Class VI, MEM Elution or other relevant tests in order to establish their biocompatibility and biostability.

The Materials of Choice



Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an implanted medical device.

Thermedics Polymer Products' polyurethanes are reaction products synthesized from diisocyanates, macrodiols and chain extenders. The characteristics of each polyurethane can be attributed to its structure. Polyurethanes are made of hard and soft domains where the diisocyanate and extender make up the hard domains and the macrodiol makes up the soft domain. Varying the ratios of these two domains allow polyurethanes to be formulated with durometers as soft as 72A or as hard as 84D (Shore Hardness).

Polyurethanes are designated aromatic or aliphatic on the basis of the chemical nature of the diisocyanate component in their formulation. Tecoflex, Tecophilic and Carbothane resins are manufactured using the aliphatic compound, hydrogenated methylene diisocyanate (HMDI). Tecothane and Tecoplast resins use the aromatic compound methylene diisocyanate (MDI). All the formulations, with the exception of Carbothane, are formulated using polytetramethylene ether glycol (PTMEG) and 1,4 butanediol chain extender. Carbothane is specifically formulated with a polycarbonate diol (PCDO). These represent the major chemical composition differences among the various families.

Aromatic and aliphatic polyurethanes share similar properties that make them outstanding materials for use in medical devices. In general, there is not much difference between medical grade aliphatic and aromatic polyurethanes with regard to the following chemical, mechanical and biological properties:

- High tensile strength (4,000 – 10,000 psi)
- High ultimate elongation (250 – 700%)
- Wide range of durometer (72 Shore A to 84 Shore D)
- Good biocompatibility
- High abrasion resistance
- Good hydrolytic stability
- Can be sterilized with ethylene oxide and gamma irradiation
- Retention of elastomeric properties at low temperature
- Good melt processing characteristics for extrusion, injection molding, etc.

With such an impressive array of desirable features, it is no wonder that both aliphatic and aromatic polyurethanes have become increasingly the material of choice in the design of medical grade components. There are, however, distinct differences between these two families of polyurethane that could dictate the selection of one over the other for a particular application:

Yellowing

In their natural states, both aromatic and aliphatic polyurethanes are clear to very light yellow in color. Aromatics, however, can turn dark yellow to amber as a result of melt processing or sterilization, or even with age. Although the primary objection to the discoloration of aromatic clear tubing or injection molded parts is aesthetic, the yellowing, which is caused by the formation of a chromophore in the MDI portion of the polymer, does not appear to affect other physical properties of the material.

Radiopaque grades of Tecothane also exhibit some discoloration during melt processing or sterilization. However, both standard and custom compounded radiopaque grades of Tecothane have been specifically formulated to minimize this discoloration.

Solvent Resistance

Aromatic polyurethanes exhibit better resistance to organic solvents and oils than do aliphatics — especially as compared with low durometer (80 – 85 Shore A) aliphatics, where prolonged contact can lead to swelling of the polymer and short-term contact can lead to surface tackiness. While these effects become less noticeable at higher durometers, aromatics exhibit little or no sensitivity upon exposure to the common organic solvents used in the health care industry.

Softening at Body Temperature

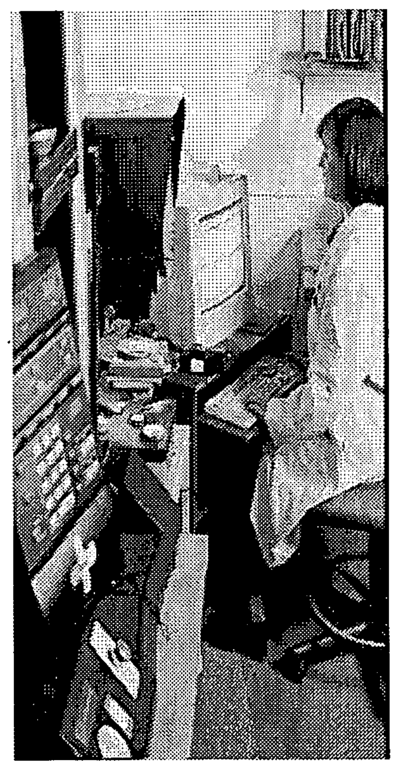
Both aliphatic and aromatic polyether-based polyurethanes soften considerably within minutes of insertion in the body. Many device manufacturers promote this feature of their urethane products because of patient comfort advantage as well as the reduced risk of vascular trauma. However, this softening effect is less pronounced with aromatic resins than with aliphatic resins.

Carcinogenic By-Products

If aromatic polyurethanes are improperly processed, such as when tubing is extruded from resin with too high a moisture content or the finished components are steam sterilized, it is possible to experience the formation of measurable amounts of methylene dianiline (MDA). MDA is listed as a carcinogen. It is not possible to form MDA with an aliphatic polyurethane. Moreover, the analogous diamine which could be formed from HMDI is not listed as a carcinogen.

Melt Processing Temperatures

Tecothane, Tecoplast and Carbothane melt at temperatures considerably higher than Tecoflex and Tecophilic. Therefore, processing by either extrusion or injection molding puts more heat history into products manufactured from Tecothane, Tecoplast and Carbothane. For example, Tecoflex EG-80A and EG-60D resins mold at nozzle temperatures of approximately 310° F and 340° F respectively. Tecothane and Carbothane products of equivalent durometers mold at nozzle temperatures in the range of 380° F to 435° F.



Thermedics strives for lot-to-lot consistency to ensure ease of processing by our customers.

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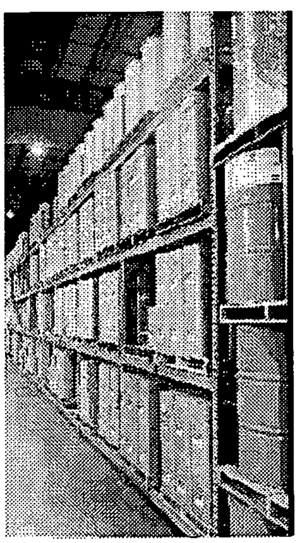

Our 30,000 square foot warehouse allows us to ship standard products from stock typically within 24 hours of receipt of your order.

Selection Guide

	TECOFLEX (polyether-based)	TECOTHANE (polyether-based)	CARBOTHANE (polycarbonate-based)	TECOPHILIC (polyether-based)	TECOPLAST (polyether-based)
Aliphatic or Aromatic	Aliphatic	Aromatic	Aliphatic	Aliphatic	Aromatic
Durometer Range	72A-83D	75A-77D	73A-75D	83A-72D	82D-84D
Radiopacifiers	Barium Sulfate Bismuth Salts Tungsten	Barium Sulfate Tungsten	Barium Sulfate Tungsten	Barium Sulfate Bismuth Salts Tungsten	N/A
Custom Colors	Yes	Yes	Yes	Limited	Yes
Solution Grades	Yes	No*	No*	Yes	No*
Extrusion and/or Injection Molding	Both	Both	Both	Both	Injection Molding (Primarily)
Melt Processing °C Temperatures Range °F	150-190 305-370	200-220 390-430	190-220 370-430	145-190 290-370	215-230 420-445
Relative Degree of Biostability	Good	Better	Best	Not Determined	Not Determined

*Tecothane, Carbothane and Tecoplast can be dissolved in organic solvents but Tecoflex and Tecophilic have grades that have been designed to dissolve more readily in these type solvents.

Radiopaque and Color Compounding

Thermedics Polymer Products' polyurethanes can be loaded with radiopaque materials for detection by X-ray or fluoroscopy and colored for product identification or coding. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixtures and superior smoothness of the final polymer. All additives are thoroughly screened and carefully tested for chemical stability, biocompatibilty and performance in the resin before use as a radiopaque or coloring agent.

Our natural grades of each family are clear (transparent) in color. The polyurethane can be made radiopaque by adding barium sulfate. Tungsten powder has also been used as an effective radiopacifier with many of our grades of resin. Bismuth subcarbonate has been used very successfully in conjunction with the Tecoflex family of products. Thermedics Polymer Products has many stock grades containing 20% and 40% barium sulfate and can custom formulate higher loadings upon request.

Transparent colors of our products can be produced using reactive dyes that chemically combine into the urethane chain, creating an unleachable covalent bond for color permanence and non-cytotoxicty. Opaque colors are formed with high-density pigment powders that are thoroughly dispersed for color uniformity and smooth consistency. Opaque colors may be chosen using a color matching chart or by matching existing components.

Custom Tubing Extrusion

Thermedics Polymer Products operates a complete tubing production facility specially designed to extrude our various polyurethane products. All Thermedics Polymer Products tubing passes strict quality control criteria at each stage of production and conforms to specifications of Good Manufacturing Practices. All tubing at Thermedics Polymer Products is produced by custom order to ensure exact dimensions and configuration.

Thermedics Polymer Products' families of polyurethane have excellent working characteristics that allow extremely small diameters and very complex lumen configurations to be extruded. Specialty operations, such as radiopaque stripe coextrusion, are done on a regular basis. Tubing requiring specific radiopaque loadings or exact color matching is also done on a regular basis allowing manufacturers to order tubing that meets their desired specifications. Thermedics Polymer Products' expert extrusion engineers have developed capabilities to extrude tubing with lumen diameters as small as .005 inch and lumen quantities up to 9 lumens. Orders of 3 to 6 lumens are not uncommon. Thermedics Polymer Products' technical staff works with clients to assure all tubing meets the tolerances and characteristics necessary to ensure top performance in its function within the medical device.

Our Commitment

The quality of Thermedic Polymer Products' family of polyurethane products reflects the expertise of the Thermedics Polymer Products' staff. This group of knowledgeable professionals stands ready to assist our customers in applying our products to both existing and next-generation requirements.

Close interaction with customers provides us with feedback essential for improving our own products. At the same time, it helps to determine improved methods that can maximize the quality and cost effectiveness of our customers' end products. Our staff is well versed in materials handling, processing methods and product design.

In a time when other manufacturers are retreating from the medical market, Thermedics Polymer Products reaffirms its commitment to continue supplying medical grade thermoplastic polyurethane resins.

Detailed product pamphlets are available to identify the unique characteristics of each of our families of polyurethane. For more information about our products or services call: 978-642-5000 or fax: 978-657-4371. Visit our web site at http://www.thermedicsinc.com.

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Thermedics Polymer Products
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Page 1

Committed to

providing medical

grade thermoplastic

polyurethane resins.

Thermedics Polymer Products

Beginning with the commercial introduction of Tecoflex in 1983, Thermedics Polymer Products has continued to supply the medical device industry with an outstanding array of thermoplastic polyurethanes (TPU's). Each of our family of products — Tecoflex , **Tecothane** , Carbothane , **Tecoplast** and Tecophilic has been specifically formulated to have good biocompatibility, flexural endurance, high strength and processing versatility over a wide range of applications. Thermedics Polymer Products' families of TPU's are now being used in many medical devices

with new applications continually being found by device manufacturers who encounter demanding tissue or blood contact situations.

Meeting the Challenge

Body tissue and blood present difficult environments for elastomeric components of ind medical devices. Such components must be able to withstand extended exposure to hostile aqu environments at body temperature and the corrosive biochemical composition of blood and bod that can degrade many materials. At the same time, the device must cause as few complications the patient as possible. Blood clotting, rejection responses, tissue inflammation and leaching of chemicals into the body must all be minimized for a material to meet the safety requirements o indwelling medical device. Furthermore, the elastomeric component must be strong and easy to manufacture into small, precise shapes and sizes specified by device designers. For example, it important to keep **catheters** as small as possible when they are entering the circulatory system common application for cardiovascular diagnostic and clinical devices.

Resins with biocompatibility and biostability are critical components in medical device manufacturing. Thermedics Polymer Products offers a wide variety of thermoplastic polyuretha are designated as medical grade biomaterials having passed either USP Class VI, MEM Elution relevant tests in order to establish their biocompatibility and biostability.

3

The Materials of Choice

Thermedics Polymer Products' polyurethanes are reaction products sy diisocyanates, macrodiols and chain extenders. The characteristics of each p attributed to its structure. Polyurethanes are made of hard and soft domains w and extender make up the hard domains and the macrodiol makes up the sof ratios of these two domains allow polyurethanes to be formulated with durom as hard as 84D (Shore Hardness).

Polyurethanes are designated aromatic or aliphatic on the basis of the diisocyanate component in their formulation. Tecoflex, Tecophilic and Carb manufactured using the aliphatic compound, hydrogenated methylene diisoc and **Tecoplast** resins use the aromatic compound methylene diisocyanate (M with the exception of Carbothane, are formulated using polytetramethylene e 1,4 butanediol chain extender. Carbothane is specifically formulated with a p These represent the major chemical composition differences among the vario

Blood clotting, rejection responses, tissue inflammation and leaching of toxic chemicals into the body must all be minimized for a material to meet the safety requirements of an implanted medical device.

Aromatic and aliphatic polyurethanes share similar properties that ma materials for use in medical devices. In general, there is not much difference aliphatic and aromatic polyurethanes with regard to the following chemical, properties:

- High tensile strength (4,000 – 10,000 psi)
- High ultimate elongation (250 – 700%)
- Wide range of durometer (72 Shore A to 84 Shore D)
- Good biocompatibility
- High abrasion resistance
- Good hydrolytic stability
- Can be sterilized with ethylene oxide and gamma irradiatio
- Retention of elastomeric properties at low temperature

• Good melt processing characteristics for extrusion, injectio

With such an impressive array of desirable features, it is no w and aromatic polyurethanes have become increasingly the material of choice grade components. There are, however, distinct differences between these tw polyurethane that could dictate the selection of one over the other for a parti

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Yellowing

In their natural states, both aromatic and aliphatic polyurethanes are clear to very light yellow in color. Aromatics, however, can turn dark yellow to amber as a result of melt processing or sterilization, or even with age. Although the primary objection to the discoloration of aromatic clear tubing or injection molded parts is aesthetic, the yellowing, which is caused by the formation of a chromophore in the MDI portion of the polymer, does not appear to affect other physical properties of the material.

Radiopaque grades of **Tecothane** also exhibit some discoloration during melt processing or sterilization. However, both standard and custom compounded radiopaque grades of **Tecothane** have been specifically formulated to minimize this discoloration.

Solvent Resistance

Aromatic polyurethanes exhibit better resistance to organic solvents and oils than do aliphatics — especially as compared with low durometer (80 – 85 Shore A) aliphatics, where prolonged contact can lead to swelling of the polymer and short-term contact can lead to surface tackiness. While these effects become less noticeable at higher durometers, aromatics exhibit little or no sensitivity upon exposure to the common organic solvents used in the health care industry.

Softening at Body Temperature

Both aliphatic and aromatic polyether-based polyurethanes soften considerably within minutes of insertion in the body. Many device manufacturers promote this feature of their urethane products because of patient comfort advantage as well as the reduced risk of vascular trauma. However, this

because of patient comfort advantage as well as the reduced risk of vascular trauma. However, this softening effect is less pronounced with aromatic resins than with aliphatic resins.

Carcinogenic By-Products

If aromatic polyurethanes are improperly processed, such as when tubing is extruded from resin with too high a moisture content or the finished components are steam sterilized, it is possible to experience the formation of measurable amounts of methylene dianiline (MDA). MDA is listed as a carcinogen. It is not possible to form MDA with an aliphatic polyurethane. Moreover, the analogous diamine which could be formed from HMDI is not listed as a carcinogen.

Melt Processing Temperatures

Tecothane, **Tecoplast** and Carbothane melt at temperatures considerably higher than Tecoflex and Tecophilic. Therefore, processing by either extrusion or injection molding puts more heat history into products manufactured from **Tecothane, Tecoplast** and Carbothane. For example, Tecoflex EG-80A and EG-60D resins mold at nozzle temperatures of approximately 310° F and 340° F respectively. **Tecothane** and Carbothane products of equivalent durometers mold at nozzle temperatures in the range of 380° F to 435° F.

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The TPU Product Family

Each of our families of resins has unique characteristics that must be conside

material for your application. The following summaries will guide you in the material for your specific needs.

Tecoflex ®

A family of aliphatic, polyether-based TPU's available over a wide range of radiopacifiers. These resins are easy to process and do not yellow upon agin are candidates to replace latex. Caution must be observed in evaluating these low durometer grades, in long-term implant applications because of the pote

Tecothane ®

A family of aromatic, polyether-based TPU's available over a wide range of radiopacifiers. One can expect **Tecothane** resins to exhibit improved solven when compared with Tecoflex resins of equal durometers. As with any arom **Tecothane** resins tend to yellow upon aging or when subjected to radiation s

Carbothane ®

A family of aliphatic, polycarbonate-based TPU's available over a wide rang and radiopacifiers. This type of TPU has been reported to exhibit excellent o which may equate to excellent long-term biostability. This family, like Teco does not yellow upon aging.

Tecophilic ®

A family of aliphatic, polyether-based TPU's which have been specially form equilibrium water contents of up to 150% of the weight of dry resin. Extrusi designed to provide maximum physical properties of thermoformed tubing o Solution grade formulations are designed to provide greater solubility in org lacquers for coating applications. Tecogel, a new member to the Tecophilic can be formulated to absorb equilibrium water contents between 500% and 2 dry resin. The materials were designed as a coating cast from an ethanol/wat solvent systems such as THF/water and DMAC can be used. Tecogel is melt injection molding and extrusion methods.

Tecoplast ®

A family of aromatic, polyether-based TPU's formulated to produce rugged components exhibiting high durometers and heat deflection temperatures. **Te** as hubs and fittings manufactured as individual components or insert molded clear as well as transparent and opaque colors.

Our 30,000 square foot warehouse allows us to ship standard products from stock typically within 24 hours of receipt of your order.

Selection Guide

	TECOFLEX (polyether-based)	**TECOTHANE** (polyether-based)	CARBOTHANE (polycarbonate-based)	TEC (polye
Aliphatic or Aromatic	Aliphatic	Aromatic	Aliphatic	Aliph
Durometer Range	72A-83D	75A-77D	73A-75D	83A-
Radiopacifiers	Barium Sulfate Bismuth Salts Tungsten	Barium Sulfate Tungsten	Barium Sulfate Tungsten	Bariu Bism Tung
Custom Colors	Yes	Yes	Yes	Limi
Solution Grades	Yes	No*	No*	Yes
Extrusion and/or Injection Molding	Both	Both	Both	Both
Melt Processing °C Temperatures Range °F	150-190 305-370	200-220 390-430	190-220 370-430	145- 290-
Relative Degree of Biostability	Good	Better	Best	Not D

*Tecothane, Carbothane and Tecoplast can be dissolved in organic solvents but Tecoflex and Tecophilic have grades that have been designed to di solvents.

Radiopaque and Color Compounding

Thermedics Polymer Products' polyurethanes can be loaded with radiopaque materials for detection by X-ray or fluoroscopy and colored for product identification or coding. All radiopaque or color additives are introduced and dispersed at the time of polymerization, creating extremely consistent mixtures and superior smoothness of the final polymer. All additives are thoroughly screened and carefully tested for chemical stability, biocompatibilty and performance in the resin before use as a radiopaque or coloring agent.

Our natural grades of each family are clear (transparent) in color. The polyurethane can be made radiopaque by adding barium sulfate. Tungsten powder has also been used as an effective radiopacifier with many of our grades of resin. Bismuth subcarbonate has been used very successfully in conjunction with the Tecoflex family of products. Thermedics Polymer Products has many stock grades containing 20% and 40% barium sulfate and can custom formulate higher loadings upon request.

Transparent colors of our products can be produced using reactive dyes that chemically combine into the urethane chain, creating an unleachable covalent bond for color permanence and non-cytotoxicty. Opaque colors are formed with high-density pigment powders that are thoroughly dispersed for color uniformity and smooth consistency. Opaque colors may be chosen using a color matching chart or by matching existing components.

Custom Tubing Extrusion

Thermedics Polymer Products operates a complete tubing production facility specially designed to extrude our various polyurethane products. All Thermedics Polymer Products tubing passes strict quality control criteria at each stage of production and conforms to specifications of Good Manufacturing Practices. All tubing at Thermedics Polymer Products is produced by custom order to ensure exact dimensions and configuration.

configuration.

Thermedics Polymer Products' families of polyurethane have excellent working characteristics that allow extremely small diameters and very complex lumen configurations to be extruded. Specialty operations, such as radiopaque stripe coextrusion, are done on a regular basis. Tubing requiring specific radiopaque loadings or exact color matching is also done on a regular basis allowing manufacturers to order tubing that meets their desired specifications. Thermedics Polymer Products' expert extrusion engineers have developed capabilities to extrude tubing with lumen diameters as small as .005 inch and lumen quantities up to 9 lumens. Orders of 3 to 6 lumens are not uncommon. Thermedics Polymer Products' technical staff works with clients to assure all tubing meets the tolerances and characteristics necessary to ensure top performance in its function within the medical device.

Page 9

Our Commitment

The quality of Thermedic Polymer Products' family of polyurethane products reflects of the Thermedics Polymer Products' staff. This group of knowledgeable professionals stand assist our customers in applying our products to both existing and next-generation requireme

Close interaction with customers provides us with feedback essential for improving o products. At the same time, it helps to determine improved methods that can maximize the q

products. At the same time, it helps to determine improved methods that can maximize the q cost effectiveness of our customers' end products. Our staff is well versed in materials handl processing methods and product design.

In a time when other manufacturers are retreating from the medical market, Thermed Products reaffirms its commitment to continue supplying medical grade thermoplastic polyu resins.

Detailed product pamphlets are available to identify the unique characteristics of each families of polyurethane. For more information about our products or services call: 978-642 fax: 978-657-4371. Visit our web site at http://www.thermedicsinc.com.

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